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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,847

12/09/2005

Richard Joseph Fagan

C&R-107

5016

23557 7590 07/21/2008  
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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

07/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,847	<b>Applicant(s)</b> FAGAN ET AL.	
	<b>Examiner</b> CHIH-MIN KAM	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 75-124 is/are pending in the application.
- 4a) Of the above claim(s) 104-124 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75,78,79,81,82,85,86,88,89,92,93 and 96-103 is/are rejected.
- 7) ☒ Claim(s) 76,77,80,83,84,87,90,91 and 94 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/28/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Match</u> .                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 47 a), i), j), 48, 49a), i), 54, 55, 62, 63 and 73-74, SEQ ID NO:34 as the amino acid sequence, and viral or acute liver disease including alcoholic liver failure as the disease, in the response to restriction requirement filed March 17, 2008 is acknowledged. In the response, claims 1-74 have been cancelled, and new claims 75-124 have been added. Since claims 104-124, which are directed to polynucleotides, belong to group 2, thus they are withdrawn from consideration. Therefore, claims 75-103 are examined.

### ***Informalities***

The disclosure is objected to because of the following informalities:

2. Figs. 1, 3-8, 10, 11 and 13 contain many amino acid and nucleotide sequences, however, these sequences are not identified by "SEQ ID NO:" either in the drawings or in the brief description of the drawings. Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to identify all the sequences in the specification and to include all the sequences in the sequence listing. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1656

3. Claims 96-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 96-103 are indefinite because the claims lack an essential step in the method of treating viral or acute liver disease. The omitted step is the outcome of the treatment, it is not clear what result the effect amount of pharmaceutical composition would produce. Claims 97-103 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 75, 78, 79, 81, 82, 85, 86, 88, 89, 92, 93 and 95 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as

Art Unit: 1656

obvious over Hu *et al.* (WO 02/066624, listed in IDS filed 8/28/06; published August 29, 2002; filed February 19, 2002).

Hu *et al.* teach identification and characterization of a nucleotide (SEQ ID NO:1) that encodes a novel human protein (NHP) having the amino acid sequence of SEQ ID NO:2 (436 amino acids), which shares structural similarity with metalloproteases and having protease activity (page 2, lines 2-12; page 22, lines 9-16; page 34, claim 4 of the WO document), and has 95.7% sequence identity to the amino acid sequence of SEQ ID NO:34 (See attached sequence match; claims 75 and 78). Hu *et al.* also teach labeled NHP fusion proteins such as alkaline phosphatase-NHP, NHP- alkaline phosphatase or NHP-IgFc fusion proteins (page 15, lines 6-10; page 17, lines 7-9; claims 79 and 81). Since the reference also teaches the NHP products can be used as therapeutics, e.g., administration of an effective amount of a soluble NHP, a NHP-IgFc fusion proteins, or NHP antibody (page 17, lines 5-17; page 29, lines 9-17), it would be obvious to the person of skill in the art that a pharmaceutical or immunogenic composition comprising NHP, NHP-IgFc fusion proteins, or NHP antibody would be prepared (claims 82, 85, 86, 88, 89, 92, 93 and 95).

### ***Claim Objections***

5. Claims 76, 77, 80, 83, 84, 87, 90, 91 and 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

6. Claims 75, 78, 79, 81, 82, 85, 86, 88, 89, 92, 93 and 96-103 are rejected; and claims 76, 77, 80, 83, 84, 87, 90, 91 and 94 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

July 17, 2008